

### **REMARKS / ARGUMENTS**

The action by the Examiner of this application, together with the cited references, has been given careful consideration. Following such consideration, claims 3, 5, and 6 remain unchanged, claim 2 has been cancelled, and claims 1, 3 and 4 have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention is directed to a method for microbially deactivating items, such as medical, dental, pharmaceutical, veterinary or mortuary instruments and devices, using a liquid microbial deactivation system. Typically, the items to be deactivated are placed within a container that is placed within a deactivation chamber of a reprocessor. Following a deactivation cycle, the deactivated items are manually removed from the container. No matter how carefully the items are removed from the reprocessor, the items are exposed to airborne bio-contaminants in the surrounding atmosphere.

The present invention provides a method of microbially deactivating items in a sealable container. The present invention also provides a method of storing the deactivated items for a prolonged period of time in the sealable container in a location remote from the reprocessor. The container includes fluid access ports that have a normally closed position and an open position. The fluid access ports are moveable to the open position *by contacting actuating means on the reprocessor*. When the container is removed from the reprocessor following a deactivation cycle, the *fluid access ports move* to, i.e., assume, the normally closed position. In this manner, the container is sealed and the medical instruments contained therein are protected from biological contamination. The items can be stored in the container until they are used again.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a method of microbially deactivating items as presently set forth in the claims, or the advantages thereof.

In response to the Examiner's rejections, claim 1 has been amended to add a new step (now step c)) that reads "causing said fluid access ports in said container to engage actuating

means on said reprocessor wherein engagement of said fluid access ports with said actuating means moves said fluid access ports to said open position....” A step of “disengaging” (step f)) has also been added to claim 1 and reads: “disengaging said fluid access ports from said actuating means on said reprocessor during said step e) of removing....”

Claim 4 has been amended to include a step of “causing said fluid access port to move to said open position from said normally closed position *by contacting actuating means on said reprocessor as said container is placed into said reprocessor.*” Claim 4 has also been amended to include a step of “causing said fluid access port to move to said normally closed position *when said fluid access port no longer contacts said actuating means.*”

The Examiner has rejected claims 4-6 under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, under 35 U.S.C. 103, as being obvious in view of, U.S. Patent No. 6,919,057 to Halstead et al.

Halstead et al. ‘057 discloses a method for deactivating an endoscope in an automated reprocessor. The reprocessor is dimensioned to receive a container that includes an internal chamber for receiving an endoscope head. The endoscope head is placed within the chamber and the container is placed within the reprocessor. The endoscope includes a cord that extends from the chamber through an outlet. A gasket assembly that is made up of resilient, flexible fins is disposed in the outlet to define a restricted fluid passage around the cord. During reprocessing, a small portion of fluid flows through the fluid passage around the cord. The slowly leaking liquid insures that all exterior surfaces of the endoscope are in contact with the reprocessing liquid. Thus Halstead et al. ‘057 does not disclose a *sealable* container dimensioned to receive an entire endoscope. Instead, Halstead et al. ‘057 discloses a container that is dimensioned to receive only a portion of an endoscope and to allow another portion of the endoscope to extend from the container. In this regard, the container disclosed in Halstead et al. ‘057 is *not sealable*.

Halstead et al. ‘057 does not teach, suggest, or show a step of “causing said fluid access port to move to said open position from said normally closed position by contacting actuating means on said reprocessor as said container is placed into said reprocessor” as required in step c) of claim 4. In this regard, the gasket assembly of the Halstead et al. ‘057 reference

does not have a normally closed position. When an endoscope is not disposed within the container of Halstead et al. '057, the gasket assembly simply defines two open channels between flexible fins. When an endoscope is placed within the container of Halstead et al. '057 and the *container* is closed, the gasket assembly *remains open* such that "a flow of reprocessing liquid leaks out of the housing through the fin openings insuring that all exterior surfaces are contacted with the cleaning and disinfectant liquids" (column 6, line 67 through column 7, line 3 of Halstead et al. '057). The gasket assembly of Halstead et al. '057 is not disclosed as contacting an actuating means when a container is placed into a reprocessor. In this regard, the gasket assembly of Halstead et al. '057 is not disclosed as contacting any portion of the reprocessor or anything else other than a portion of an endoscope that extends therethrough. Stated another way, the gasket assembly disclosed in Halstead et al. '057 is not caused to move to an open position when the container is placed within a reprocessor. The gasket assembly of Halstead et al. '057 is not caused to move by placing the container within a reprocessor and the gasket assembly does not have a normally closed position.

Applicants respectfully submit that when Applicants referred to a container being closed above and in the Response dated July 6, 2006, the Applicants were referring to the two sections of the container and not to the gasket assembly of the container. In this respect, the gasket assembly as disclosed in Halstead et al. '057 always remains open.

Claims 5 and 6 depend from claim 4. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 4.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead et al. '057. Referring now to claim 1, Halstead et al. '057 does not teach, suggest, or show a step of "causing said fluid access ports in said container to engage actuating means on said reprocessor." In this regard, as discussed above regarding claim 4, the gasket assembly disclosed in Halstead et al. '057 is not disclosed as contacting anything other than a portion of the endoscope.

Further, Halstead et al. '057 does not teach, suggest, or show a step of "disengaging said fluid access ports from said actuating means on said reprocessor during said

step of removing” as required by claim 1 of the present application. Because Halstead et al. ‘057 does not teach a fluid access port that contacts an actuating means of a reprocessor, Halstead et al. ‘057 cannot teach a step of disengaging from an actuating means on a reprocessor.

The Examiner states that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position....” Applicants respectfully submit that Halstead et al. ‘057 does not disclose a container capable of being closed such that an endoscope contained therein is not damaged during reprocessing. In this regard, the container of Halstead encloses only a portion of the endoscope and is not capable of protecting the endoscope from damage during reprocessing. In this regard, the outlet referred to by the Examiner would continue to have the light guide connector cord extending therethrough and contacting the gasket fins when the container of Halstead et al. ‘057 is removed from the reprocessor. Thus, removing the container of Halstead et al. ‘057 from a reprocessor does not cause any change in position of the outlet as required by claim 1. Further, as indicated above, the outlet does not have a normally closed position.

In the present application, claims 2 and 3 depend from claim 1. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 1.

In summary, the cited reference does not teach, suggest, or show a method for microbially deactivating items and storing the same as claimed in the present application. Halstead et al. ‘057 does not teach, suggest, or show a step of causing an access port to move from a normally closed position to an open position by contacting a reprocessor. Further, Halstead et al. ‘057 does not show a step of causing a fluid access port to move from an open position to a normally closed position upon removal of a container from a reprocessor.

The cited references made of record and not relied upon have also been reviewed. It is respectfully submitted that none of these additional references teaches, suggests, or shows Applicants’ invention as defined by the present claims.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters

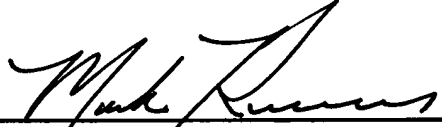
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Response dated October 13, 2006  
OUTSTANDING OFFICE ACTION dated August 30, 2006

that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8630US.

Respectfully submitted,

Date: October 13, 2006

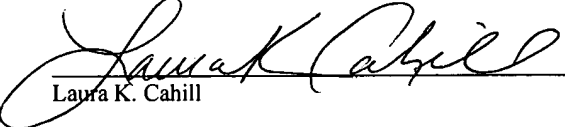
  
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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8**

I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: October 13, 2006

  
Laura K. Cahill